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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/815,577	03/23/2001	Brittan L. Pasloske	AMBI:054US/MBW	7249

7590 11/20/2003

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EXAMINER
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CRANE, LAWRENCE E

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 11/20/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. <b>09/815,577</b>	Applicant(s) <b>Pasloske et al.</b>	
	Examiner <b>L. E. Crane</b>	Group Art Unit <b>1623</b>	

**- THE MAILING DATE of this communication appears on the cover sheet beneath the correspondence address -**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE **--3--** MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be filed after six months from the date of this communication.
- If the prior for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 USC §133).

### Status

- ☒ Responsive to communication(s) filed on **-08/21/03 (RCE, amdt C & Terminal Disclaimer)-**.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- ☒ Claims **---54, 56-73, 75-81, 83-87, 91-96, 98-114 and 118-121---** are pending in the application. Claims **-82, 88-90, 97 and 115-117-** have been cancelled.

Of the above claim(s) **---[]---** is/are withdrawn from consideration.

- ☐ Claim(s) **---[]---** is/are allowed.
- ☒ Claims **---54, 56-73, 75-81, 83-87, 91-96, 98-114 and 118-121---** are rejected.
- ☐ Claim(s) **---[]---** is/are objected to.
- ☐ Claim(s) **---[]---** are subject to restriction or election requirement.

### Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☒ The proposed drawings, filed on **-03/23/01-** are ☒ approved ☐ disapproved.
- ☐ The drawing(s) filed on **-[]-** is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119(a)-(d)

- ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).
- ☒ All ☐ Some ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) **-[]-**.
- ☒ received in the national stage application from the International Bureau (PCT Rule 17.2(a)).
- \* Certified copies not received: **-[]-**.

### Attachment(s)

- |   |   |
|---|---|
| <input type="checkbox"/> Information Disclosure Statement(s), PTO-1449, Paper No(s). <u><b>---[]---</b></u> | <input type="checkbox"/> Interview Summary, PTO-413                     |
| <input checked="" type="checkbox"/> Notice of Reference(s) Cited, PTO-892                                   | <input type="checkbox"/> Notice of Informal Patent Application, PTO-152 |
| <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review, PTO-948                            | <input type="checkbox"/> Other: <u><b>-[]-</b></u>                      |

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Claims 82, 88-90, 97 and 115-117 have been cancelled, claims 54, 61, 69, 71-73, 80, 86, 87, 114, 118 and 120 have been amended, and new claim 121 has been added as per the amendment filed August 21, 2003. No additional Information Disclosure Statements (IDSs) have been filed as of the date of this Office action. A Terminal Disclaimer also filed August 21, 2003 has been received, reviewed, accepted and made of record.

Claims 54, 56-73, 75-81, 83-87, 91-96, 98-114 and 118-121 remain in the case.

Claims 73, 75-79, 98, 104-114, 118 and 120 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

In the claims listed, the implied meaning is that the instant claimed reverse RNA transcription process will apply to any and all ribonuclease-containing mixtures causing inactivation of all of the ribonucleases therein, when it is very clear from the **Khesin et al.** reference (PTO-892 ref. Y) that some ribonucleases actually achieve enhanced activity following reduction by a thiol-containing reducing agent. For this reason the functionality of applicant's written description is deemed to have failed to describe the invention accurately. The instant claims are rejected because the noted, functional-definition-derived, implied inaccuracy is also present therein as well.

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Applicant's arguments with respect to claims **54, 56-73 and 75-120** have been considered but are moot in view of the new grounds of rejection.

5        Claims **73, 75-79, 98, 104-114, 118 and 120** are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one of ordinary skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

10        The fundamental issue here is whether practicing the full scope of the instant invention is possible without undue experimentation. As provided for in *In re Wands* (858 F.2d 731, 737; 8 USPQ 2d 1400, 1404 (Fed Cir. 1988) the minimum factors to be considered in determination of whether a conclusion of "undue experimentation" is appropriate are as follows:

15        A. The breadth of the claims is large with regard to the ribonucleases which said claims imply will be inactivated by the failure of said claims to specify any specific ribonucleases as being the subject of inactivation by thiol-mediated reduction .

20        B. The nature of the invention is directed to the transcription of RNA into complementary DNA by contacting an RNA containing sample with DNA monomers in the presence of a reverse transcriptase.

C. The state of the prior art is well established by the instant cited references.

25        D. The level of one or ordinary skill is high because one or ordinary skill must understand how to isolate RNA containing samples and

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conduct the enzymatic process disclosed. Examiner assumes that at least a Masters or possibly a Ph.D. level practitioner would be required.

5 E. The level of predictability in the art is low as revealed by the **Khesin et al.** reference (PTO-892 ref. Y) wherein it is disclosed that certain ribonucleases display increased enzymatic activity following contact with thiol-containing reducing agents.

F. The amount of direction provided by the inventor is limited to the inactivation of three common ribonucleases, specifically RNase A, RNase 1 and RNase T1,

10 G. The existence of working examples is limited to showing of how the RNases listed immediately above may be inactivated by contacting same with a thiol-containing reducing agent.

15 H. The quantity of experimentation needed to make or use the invention based on the content of the disclosure is deemed to be excessive because applicant has not provided sufficient guidance to the ordinary practitioner to permit said practitioner to practice the instant claimed process with a reasonable expectation of success in the presence of all known ribonucleases. For this reason examiner respectfully suggests that applicant should limit the instant claimed  
20 press to the ribonucleases listed above, in the absence of a convincing showing that extrapolation to other ribonuclease-containing RNA samples is supported by adequate experimental or theoretical guidance.

25 Applicant's arguments with respect to claims 54, 56-73 and 75-120 have been considered but are moot in view of the new grounds of rejection.

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Claims 58, 92 and 99 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5 In claim 58, 92 and 99 the term "further defined" is technically incorrect because said claims lack proper antecedent basis in claims from which they depend. Did applicant intend the term to read -- further comprising --?

10 Applicant's arguments with respect to claims 54, 56-73 and 75-120 have been considered but are moot in view of the new grounds of rejection.

Claims 92, 96, 99 and 111 are rejected under 35 U.S.C. §112, fourth paragraph, as being of improper dependent form for failing to further limit the subject matter of a previous claim.

15 Applicant's arguments with respect to claims 54, 56-73 and 75-120 have been considered but are moot in view of the new grounds of rejection.

Claims 54, 56-57, 59-72, 80-87, 91, 93-97, 100-103, and 119 appear to be allowable as submitted.

20 Claims 58, 73, 75-79, 92, 98-99, 104-114, 118 and 120 would be allowable if rewritten or amended to overcome the rejection under 35 U.S.C. 112.

25 Claim 121 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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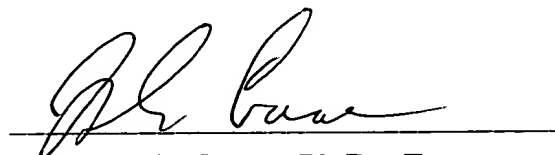
Papers related to this application may be submitted to Group 1600 via facsimile transmission(FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone numbers for the FAX machines  
5 operated by Group 1600 are (703) 308-4556 and 703-305-3592.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is 703-308-4639. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through  
10 Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson, can be reached at (703)-308-4624.

Any inquiry of a general nature or relating to the status of this  
15 application should be directed to the Group 1600 receptionist whose telephone number is 703-308-1235.

LECrane:lec  
11/18/03



L. E. Crane, Ph.D., Esq.  
Patent Examiner  
Technology Center 1600